

INTERVENTION

Abdominal aorta aneurysm with hostile neck: Early outcomes in outside instruction for use in patients using the treovance[®] stent graft

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Abstract

Purpose: The efficacy and safety of endovascular aneurysm repair (EVAR), in patients outside instruction for use (IFU), is very challenging and widely debated. The aim of this study was to evaluate the placement of the Treovance[®] abdominal aorta stent-graft in patients with hostile proximal necks considered outside IFU. **Materials and Methods:** Between May 2013 and August 2014, 5 patients with outside IFU underwent EVAR with the Treovance[®] stent-graft. Technical and clinical successes were evaluated. All 5 patients underwent clinical and imaging follow-up. **Results:** Technical and clinical successes were achieved in all 5 patients without adjunctive endovascular procedures or surgical conversion. During the mean follow-up of 21 months, no type I/III endoleaks, stent-graft migration nor kinking/occlusion were observed. In all 5 patients, a reduction of the proximal neck angle was observed. **Conclusion:** In our small series of selected outside IFU patients, EVAR with the Treovance[®] stent-graft was technically feasible and safe, with satisfactory short-term follow-up results, when performed by experienced operators. Long-term follow-up will be necessary to confirm the durability of our preliminary promising results.

Key words: Abdominal aortic aneurysm; endovascular aneurysm repair; instruction for use; proximal aortic neck; Treovance[®] stent-graft

Introduction

Treatment of abdominal aortic aneurysm (AAA) with hostile proximal neck anatomy remains an important major limitation for endovascular aneurysm repair (EVAR).^[1] The safety and efficacy of standard EVAR in patients with unfavorable proximal neck remains controversial due to the inadequate sealing and the need for intraoperative or late endovascular adjunctive procedures.^[2-5] Numerous

reports describe difficulties performing conventional EVAR in patients with AAA with hostile neck anatomy.^[6-8] However, improvement in endovascular technology and the experience and expertise of endovascular specialists has modified the management of AAA patients with an improvement in perioperative outcomes and late results. Conversely, increasing number of papers describe successful treatment of AAA patients with proximal necks

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that are outside specific instructions for use (IFU) using conventional stent-grafts.^[2,3,5-8] The aim of our study is to evaluate the performance, safety, and efficacy of the Treovance® stent-graft (Bolton Medical, Sunrise, FL, USA) in AAA patients with hostile proximal necks anatomy that are considered outside IFU.

Materials and Methods

Device description

The Treovance® (Bolton Medical, Sunrise, FL, USA) is a suprarenal fixation endovascular stent-graft made by serpentine self-expanding Nitinol stents sutured to a polyester vascular graft. The bottom of the proximal bare stent is partially overlapped with the first covered stent providing a wider sealing line. There are double proximal level barbs: the first one on the top (suprarenal barbs) and the second one on the bottom (infrarenal barbs) of the proximal bare stent [Figure 1]. The suprarenal barbs are covered by the tip-capture clasp system, whereas the infrarenal barbs are hidden in the fold of the first covered stent till complete deployment of the main body. Thus, until the proximal bare stent is completely released, the fixation barbs are inactive, which allows safe manipulation and repositioning (caudally or cranially) of the stent-graft system.^[9-11] This double level of proximal barbs leads to optimal fixation even in short length and angulated proximal neck anatomy. IFU guarantees to treat necks as short as 10 mm or up to 60° of angulation; 61–75° neck angulation require a minimum length of 15 mm.

There are also 5 dull barbs on each main body limb designed to automatically engage the limb extension, guaranteeing a definitive fixation and secure attachment between the two modules (main body and limb extension).^[9-11]

The main body delivery system has a double control: a controlled gear system operated by rotating a turn

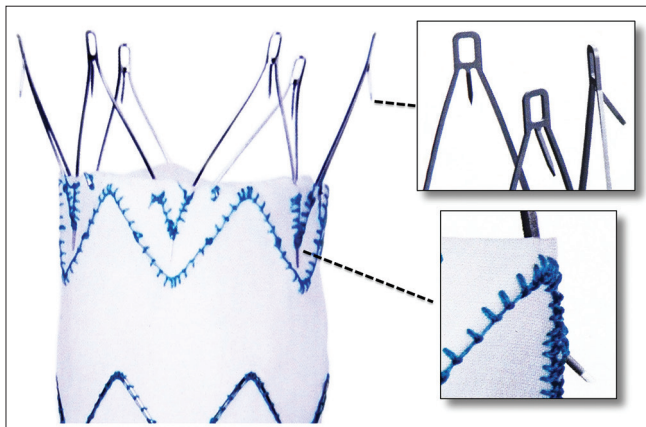


Figure 1: Main body proximal part of the Treovance® abdominal aorta stent-graft. The upper-right inset picture shows the detail of the proximal bare-stent with suprarenal barbs; the lower-right inset picture shows the detail of the proximal covered stent with infrarenal barbs

knob (precise deployment) and a pull system operated by pulling back the turn knob (quick deployment). The main body delivery system has profile of 18 Fr for diameters from 20 mm to 28 mm and of 19 Fr for diameters up to 36 mm. The limb extension delivery system has a profile of 13 Fr for diameters from 8 mm to 15 mm and of 14 Fr for diameters up to 24 mm.

Patient selection

Between May 2013 and August 2014, 5 patients underwent EVAR with the Treovance® stent-graft. All 5 patients were enrolled for their outside IFU proximal neck anatomy according to the following criteria: (a) neck length shorter than 10 mm or angulation over 60°, (b) neck length shorter than 15 mm with an angulation ranging 61–75°. A retrospective review of a prospectively collected database of these 5 patients was performed. All 5 patients did not have significant calcification and thrombus in their necks.

Technical success was defined as correct stent-graft deployment without evidence of endoleaks, luminal stenosis, stent-graft kinking/occlusion, and need for secondary intervention (endovascular or surgical). Clinical success was defined as no aneurysm expansion, type I/III endoleak, and stent-graft migration and kinking/occlusion.

The procedures were approved by the Institutional Review Board, and written informed consent was obtained from each patient, despite having anatomical features outside recommendations of the IFU. All patients were well informed that in case of failure they would undergo adjunctive procedure as branched EVAR, fenestrated EVAR, or Chimney and Periscope technique.^[12,13]

All 5 patients underwent clinical (1 month, 3 months, 6 months, 12 months, and then every 6 months) and imaging follow-up with multidetector computed tomography (MDCT) examinations (before discharge, 3 months, 6 months, and 12 months). The first 4 patients, after the 12 months, started an ultrasound imaging follow-up.

Preoperative planning

Contrast-enhanced MDCT was performed using 128-slices (Somatom Definition AS, Siemens, Erlangen, Germany) at a thickness of 0.6 mm. All analyses (diameter, length, and angle) were performed on a dedicated workstation (Aquarius iNuition, Terarecon, San Mateo, CA, USA) with centre line reconstruction.

AAA anatomy evaluation (preprocedural and on follow-up) included maximum aorta diameter, neck diameter and length, neck angulation, neck calcifications and thrombus, iliac diameter, and length. Functional proximal neck length was defined as the distance from the lower renal artery to

the aneurysm. Proximal neck angle was defined as the angle between the proximal neck and the aneurysm [Figure 2A-C].

Preoperative determination of the most optimal C-arm position with craniocaudal and right and left anterior oblique projections were evaluated to guarantee the maximal sealing and fixation of the stent-graft in the hostile proximal neck. All stent-graft devices were oversized by 15–20%.

Endovascular procedure

All procedures were performed in a dedicated hybrid angiography suite with the use of high-resolution imaging (Artis Zee, Siemens, Erlangen, Germany). In all patients, spinal anesthesia was performed with bilateral surgical access of common femoral arteries. Based on preoperative planning, the flat-panel was angulated orthogonally to the aortic neck and orthogonally to the lower renal artery. Subsequently, an abdominal aortogram was obtained to confirm the correct location of the AAA proximal neck [Figure 3A].

Under fluoroscopic guidance and the angiographic overlay technique, the Treovance® main body stent-graft was positioned and partially deployed. Only after intraprocedural angiography that ensured the correct alignment of the markers of the proximal covered stent below the lower-most renal artery [Figure 3B], was the main body stent-graft completely deployed. The procedure was completed with the positioning and deployment of iliac limb extensions and moulding-balloon dilatation of the proximal part, iliac junction site, and distal part of the stent-graft. A final abdominal aorta angiogram was performed to evaluate the correct positioning of the device, complete exclusion of the AAA, as well as the patency of renal arteries, abdominal aorta, and iliac arteries [Figure 3C].

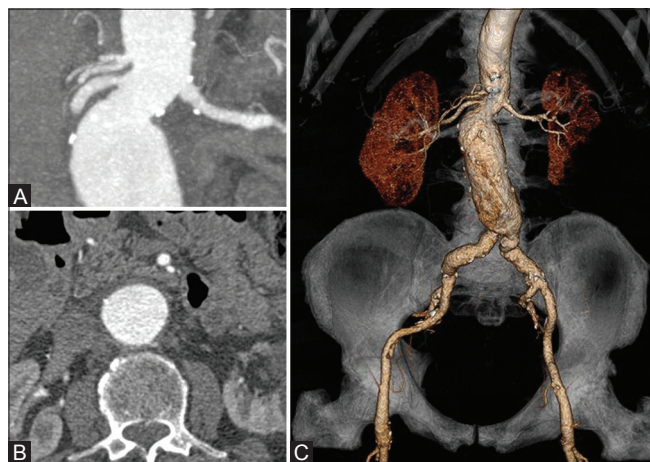


Figure 2 (A-C): Contrast-enhanced MD-CT scan images. (A) Maximum intensity projection (MIP) coronal image, at the level of the renal arteries origin, demonstrates the short length and the infrarenal angulation of the proximal neck. (B) Axial image of the abdominal aorta aneurysm. (C) Volume rendering technique (VRT) coronal image of the abdominal aorta and iliac arteries

Results

Demographic analyses of 5 patients (4 males; mean age 75 years old) with AAA with outside IFU proximal neck anatomy who were treated with Treovance® stent-graft is summarized in Table 1. Eighty percent (4/5 patients) of the patients were American Society of Anaesthesiologist (ASA) grade III/IV.

All 5 patients were classified as outside IFU following the previously described characteristics [Table 2]; 1 patient with neck length shorter than 10 mm and angulation over 60°, 2 patients with neck length shorter than 10 mm, and 2 patients with neck length shorter than 15 mm with an angulation ranging 61–75°. All 5 patients had very limited or no calcifications and thrombus at the level of the proximal neck.

Primary technical and clinical successes were achieved in all 5 patients without adjunctive endovascular procedures,

Table 1: Demographic and risk factors of 5 hostile neck anatomy patients

| | 5 patients |
|--------------------------|------------|
| Age (Years, mean) | 75.2 |
| Sex (Male, %) | 4 (80) |
| Hypertension (%) | 3 (60) |
| Diabetes mellitus (%) | 1 (20) |
| Hypercholesterolemia (%) | 2 (40) |
| Obesity (%) | 1 (20) |
| Smoke (%) | 2 (40) |
| COPD (%) | 2 (40) |
| ASA III/IV | 4 (80) |

COPD: Chronic obstructive pulmonary disease; ASA: American Society of Anaesthesiology

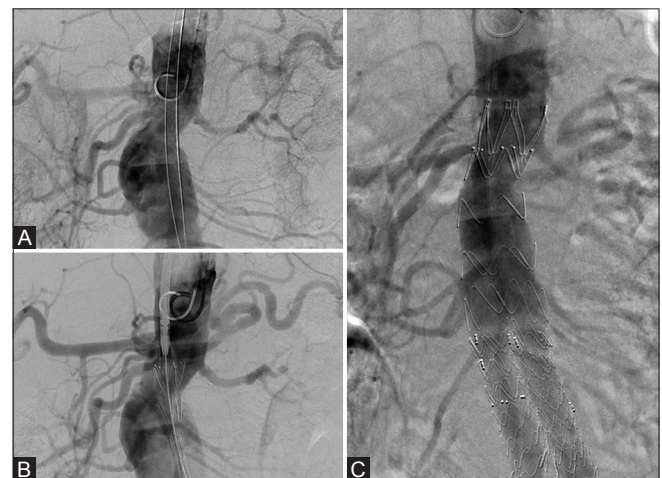


Figure 3 (A-C): Abdominal aorta angiogram images. (A) Angiography at the level of the renal arteries origin, confirms the short length and the infrarenal angulation. (B) Angiography during the release of the proximal part of the main body of the stent graft. (C) Final angiography that demonstrates the regular perfusion of the renal arteries and the complete exclusion of the abdominal aorta aneurysm

surgical conversion, type I/III endoleaks and stent-graft migration, and kinking/occlusion. All 5 patients well tolerated the procedure with a mean operation time of 87.8 minutes and a mean radiation time of 17.2 minutes [Table 3]. All patients received a total of 5000 IU intravenous heparin and a mean of 106 ml contrast medium. No patient needed blood transfusion, with an intraoperative mean blood loss of 48 ml. The postoperative course was uneventful for all 5 patients with a mean hospital stay of 4.8 days. All 5 patients were discharged with life-long mono-antiplatelet treatment (aspirin 100 mg/d). At a mean of 21 months of clinical follow-up and for all patients at least 12 months of imaging follow-up, technical and clinical success was achieved in all patients with complete AAA sac thrombosis, reduction of the proximal neck angle (mean of 35° at 6 months and of 35.8° at 12 months), as well as patency of the stent graft, renal, and iliac arteries [Table 2] [Figure 4A-C].

Discussion

EVAR is now becoming the first choice treatment in the majority of AAA patients due to the increasing number of patients with comorbidities, significant reduction of intra and postoperative mortality, improvement of stent-graft designs, and increasing clinicians' experience in EVAR techniques.^[1,14,15] This leads to the implantation

of standard stents grafts in shorter, more angulated, and wider proximal aortic necks outside IFU.^[7,8] For these patients, an adequate preoperative planning with advanced

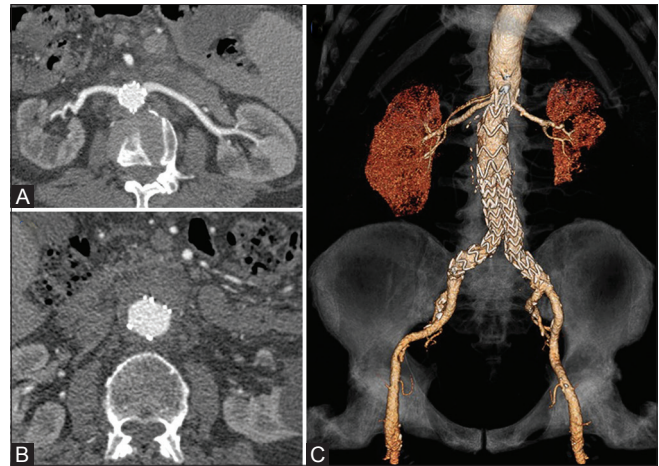


Figure 4 (A-C): Contrast-enhanced MDCT scan images on follow-up. (A) MIP axial image that demonstrates the patency of the renal arteries and the perfect sealing of the proximal bare stent. (B) Axial image of the abdominal aorta aneurysm with its complete exclusion, thrombosis and reduction in size. (C) VRT coronal image of the abdominal aorta and iliac arteries that confirms the total exclusion of the abdominal aorta aneurysm and the patency of renal and iliac arteries. Note the reduction of the infrarenal angulation of the proximal neck compared with Figure 2C

Table 2: Characteristics of AAA hostile neck that underwent EVAR Bolton IFU anatomical criteria: a) neck length shorter than 10 mm or angulation over 60°, b) neck length shorter than 15 mm with an angulation between 61-75°

| Patient Age (sex) | AAA Pre-EVAR Diameter | AAA Post-EVAR Diameter (6 m FU) | AAA Post-EVAR Diameter (12 m FU) | Neck Diameter | Functional Neck Length | Neck Angle Pre-EVAR | Neck Angle Post-EVAR (6 m FU) | Neck Angle Post-EVAR (12 m FU) |
|------------------------|-----------------------|---------------------------------|----------------------------------|---------------|------------------------|---------------------|-------------------------------|--------------------------------|
| Case 1 73 years (M) | 46 mm | 42 mm | 39 mm | 26×26 mm | 14 mm | 62° | 22° | 20° |
| Case 2 87 years (M) | 66 mm | 63 mm | 62 mm | 26×25 mm | 13 mm | 68° | 13° | 13° |
| Case 3 67 years (M) | 49 mm | 43 mm | 41 mm | 22×21 mm | 7 mm | 64° | 15° | 13° |
| Case 4 78 years (F) | 52 mm | 48 mm | 43 mm | 27×25 mm | 9 mm | 19° | 5° | 5° |
| Case 5 71 years (M) | 48 mm | 46 mm | 46 mm | 23×22 mm | 8 mm | 24° | 7° | 7° |

M: male; F: female; AAA: Abdominal Aorta Aneurysm; 6 m FU: 6 months follow-up; 12 m FU: 12 months follow-up

Table 3: Intraoperative EVAR and hospitalization details.

| Patient Age (sex) | Primary Technical Success | Adjunctive Procedure | Procedure Time (minutes) | Radiation Time (minutes) | Blood Loss (ml) | Contras Media (ml) | Hospital Stay (days) |
|------------------------|---------------------------|----------------------|--------------------------|--------------------------|-----------------|--------------------|----------------------|
| Case 1 73 years (M) | Yes | No | 119 | 22 | 80 | 145 | 5 |
| Case 2 87 years (M) | Yes | No | 67 | 12 | 35 | 90 | 4 |
| Case 3 67 years (M) | Yes | No | 83 | 17 | 40 | 115 | 3 |
| Case 4 78 years (F) | Yes | No | 79 | 15 | 50 | 100 | 8 |
| Case 5 71 years (M) | Yes | No | 91 | 20 | 35 | 80 | 4 |

M: male; F: female

workstations is mandatory, focused principally on proximal neck characteristics.^[6] This is necessary for selecting the most appropriate stent-graft to deploy it with success, with complete AAA exclusion, and to minimize possible procedure-related complications.^[2,16]

Proximal neck anatomy is the most important variable determining the suitability of EVAR and constitutes the “Achilles’ heel” of the entire procedure.^[1,2,6] Stent-graft manufacturer’s IFU regarding proximal neck anatomy are generally based on model bench test and clinical trial design, with the aim to guarantee a technical and clinical success of the procedure. Nevertheless, it is still not completely known the exact limit of safety and effectiveness to perform EVAR in AAA patients who fall outside the IFU. It was previously demonstrated that, in patients with adverse proximal neck morphology, there is a high rate of early perioperative and late graft-related adverse events.^[6,8,16-21] However, some promising midterm outcomes in outside IFU patients have been reported in the literature.^[7,8]

The continuous expanding use of EVAR, in patients with hostile AAA anatomy, has led the industry to mainly focus on technological research on the development of new stent-graft devices to overcome these challenging anatomies.^[2,3,9,16] The suprarenal fixation stent-grafts, as the Treovance[®] device has, can guarantee adequate stability and sealing in proximal aortic neck with reduced length^[1,4,7,16] due to the increased total length of the fixation. In addition the Treovance[®] device has two other technical advantages: (a) double supra- and infrarenal active barbs fixations that guarantee a circumferential ring fixation to the first stent with a resulting better conformability of the proximal sealing zone; and (b) the proximal clasping mechanism of the first stent that allows safe manipulation and repositioning of the stent-graft system till the markers of the proximal covered stent are aligned in the right position.^[9-11] All these technical characteristics, with the results of the European clinical trial design,^[9] suggested that the Treovance[®] device can be used in patients with outside IFU proximal neck anatomies. All our patients were enrolled for their serious comorbidities and because they were not candidates for open surgery.

In all 5 patients, immediately after stent-graft deployment and moulding-balloon dilatation, there was good sealing of the proximal part of the stent-graft with correct orientation that led to consequent reduction of the proximal neck angulation. The change of neck angulation pre- and postoperatively was due to two main factors: (1) the absence of significant calcification in the proximal neck (2) and the endograft’s structural conformation.

Nevertheless, it must be acknowledged that this acute reduction of neck angle after device implantation indicates that the stent graft has forced aortic conformity to the device

architecture. Whether this conformity is durable, damaging neither the device nor the aorta, requires longer follow-up. In our patient group, all these aspects were confirmed on MDCT follow-up.

The present study has two main limitations. The first limitation is the retrospective nature of the study, which by definition may result in some bias. The second and the major limitation is the short follow-up; however, we will continue surveillance of these outside IFU patients to evaluate mid and long-term results of EVAR.

Conclusions

To obtain satisfactory technical and clinical result in outside-IFU patients, accurate preoperative planning with dedicate workstations, a careful selection of the stent-graft, a hybrid operating room with high definition C-arm, and a high-volume centre with skilled operators are mandatory to perform the procedure in a safe and effective manner.

The Treovance[®] abdominal aorta endovascular stent-graft system, with its deployment system and its proximal sealing mechanism, can guarantee an atomically precise, safe, and effective deployment in patients with highly angulated and very short length necks. Our preliminary results are promising, but long terms follow-ups are necessary to confirm the benefit and the durability of treating these high-risk patients.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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